

Food and Drug Administration, HHS

§ 886.4335

test the keenness of ophthalmic surgical knives to determine whether resharpener is needed.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35606, Sept. 14, 1988; 66 FR 38813, July 25, 2001]

§ 886.4250 Ophthalmic electrolysis unit.

(a) *Identification*. An ophthalmic electrolysis unit is an AC-powered or battery-powered device intended to destroy ocular hair follicles by applying a galvanic electrical current.

(b) *Classification*. Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[55 FR 48443, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994; 66 FR 38813, July 25, 2001]

§ 886.4270 Intraocular gas.

(a) *Identification*. An intraocular gas is a device consisting of a gaseous fluid intended to be introduced into the eye to place pressure on a detached retina.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4275 Intraocular fluid.

(a) *Identification*. An intraocular fluid is a device consisting of a nongaseous fluid intended to be introduced into the eye to aid performance of surgery, such as to maintain anterior chamber depth, preserve tissue integrity, protect tissue from surgical trauma, or function as a

tamponade during retinal reattachment.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4280 Intraocular pressure measuring device.

(a) *Identification*. An intraocular pressure measuring device is a manual or AC-powered device intended to measure intraocular pressure. Also included are any devices found by FDA to be substantially equivalent to such devices. Accessories for the device may include calibrators or recorders. The device is intended for use in the diagnosis of glaucoma.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of PDP is required*. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4300 Intraocular lens guide.

(a) *Identification*. An intraocular lens guide is a device intended to be inserted into the eye during surgery to direct the insertion of an intraocular lens and be removed after insertion is completed.

(b) *Classification*. Class I (general controls). Except when used as folders or injectors for soft or foldable intraocular lenses, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 65 FR 2321, 2000]

§ 886.4335 Operating headlamp.

(a) *Identification*. An operating headlamp is an AC-powered or battery-powered device intended to be worn on the user's head to provide a light source to aid visualization during surgical, diagnostic, or therapeutic procedures.

(b) *Classification*. Class I for the battery-powered device. Class II for the